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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,744	08/18/2000	Brian F. Tack	IOWA:026US	7819

7590 08/25/2004
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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,744

Applicant(s)

TACK ET AL.

Examiner

Khatol S Shahnian-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 34-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,46 and 47 is/are rejected.
- 7) ☐ Claim(s) 34-45 and 48-55 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' amendment of 5/21/2004 is acknowledged. Claims 32-33 have been canceled. Claims 1, 3 and 34 have been amended.
2. Claims 1, 3 and 34-55 are pending.

Prior Citations of Title 35 Sections

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Objections Withdrawn

4. Objections to the drawings made in paragraph 6 of the office action mailed 7/29/2002, paper #16 are withdrawn. Applicants have filled new corrected drawings.

Rejections Moot

5. Rejection of claim 32 under 35 U.S.C. 112, second paragraph made in paragraph 9 of the office action mailed 12/15/2003, is moot in view of applicants' cancellation of said claim.
6. Rejections of claims 32-33 under 35 U.S.C. 102 (b), made in paragraphs 11-13 of the office action mailed 12/15/2003, are moot in view of applicants' cancellation of said claims.

Rejections Withdrawn

7. Rejections of claims 1 and 3 under 35 U.S.C. (102) b made in paragraph 10 of the office action mailed 12/15/2003, is withdrawn in view of applicants' amendments.

Rejections Maintained

8. Rejections of claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as

containing new matter is maintained.

The rejection was as stated below:

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims now include the newly added limitation "12-37 residues". However, there appears to be no descriptive support in the instant specification for this added limitation. 37 CFR 1.121 requires that an amendment to the claim must have antecedent basis in the original disclosure. Therefore the new limitation in the claim is considered new matter. In re Rasmussen, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04.

Applicants' arguments filed 5/21/04 have been fully considered but they are not persuasive. Applicants argue that the examiner is incorrect in stating 37 CFR 1.121. Applicants further argue that the case citation provided does not advance the examiner's case. Applicants further argue that the only evidence of the record on the issue of new matter is the Robertson declaration which the examiner has offered no rebuttal.

It is the examiner's position that 37 CFR 1.121 has been properly used in regard to new matter MPEP recites:

"In return for a patent, the inventor gives as consideration a complete revelation or disclosure of the invention for which protection is sought. All amendments or claims must find descriptive

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basis in the original disclosure, or they involve new matter. Applicant may rely for disclosure upon the specification with original claims and drawings, as filled. See also **> 37 CFR 1.121 (f)< and MPEP 608.04.”

The term “antecedent basis” recited in the rejection means that the amendments or claims **must find descriptive basis in the original disclosure.**

In response to applicants second argument that the case citation provided does not advance the examiner’s case, the examiner again refers the applicants to this section of the MPEP:

“ The proscription against the introduction of the new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information the goes beyond the subject matter originally filed. See *In re Rasmussen*, 650F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP 2163.06 through 2163.07 for a more detailed discussion of the written description requirement and its relationship to the new matter.”

In regard to Robertson declaration the examiner brings applicants’ attention to the advisory action mailed 8/26/03, which recites “Applicants’ declaration under 37 CFR 1. 132, received July 31, 2003, paper # 23 is acknowledged. The affidavit of Dr. Andrew D. Robertson has been entered and considered but does not overcome the rejection because while the specification discloses a family of antibacterial peptides, does not discloses peptides which range in size from 12-37 residues in length. The sequences of peptides recited by the specification and sequence listing are SEQ ID NOS: 1- 28 which range in size from 14-37 residues”.

In view of all the above the rejection under 35 U.S.C. 112, first paragraph, as containing new matter is proper and maintained.

New Grounds for rejection

Claim Rejections - 35 USC § 102

9. Claim 47 stand rejected under 35 U.S.C. 102(b) as being anticipated by Panorama Research Inc. (WO 94/02589). Prior art of record.

Claim 47 is drawn to an isolated antimicrobial peptide comprising an amino acid sequence (SEQ ID NO 19).

Panorama Research Inc. teaches isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 19) of the claimed invention (see abstract, page 59, claims and attached sequence alignment Accession number AAR45671). The prior art teaches the claimed invention.

10. Claims 1, 3 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Larrick et al. (Infection and Immunity, vol. 63, No. 4, pp.1291-1297, 1995).

Claims 1, 3 and 46 are drawn to isolated antimicrobial peptides comprising an amino acid sequence (SEQ ID NO 17).

Larrick et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 17) of the claimed invention (see abstract and attached sequence alignment Accession number JQ1171). Larrick et al. also teach pharmaceutical composition (see page 1296). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that

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the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

11. No claims are allowed.

Claims 1, 3, 46 and 47 stand rejected.

Claims 34-45 and 48-55 are objected to as being dependent from rejected base claim 1.

12. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

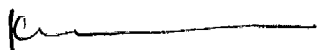
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

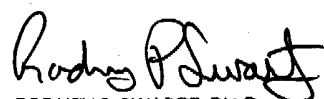


Khatol Shahnan-Shah, B.S. Pharm, M.S.

Biotechnology Patent Examiner

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August 23, 2004



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER